

## **REMARKS**

### **Amendments to the Claims**

Claim 1 has been amended to recite foamable alcohol compositions comprising greater than 40% v/v of a C<sub>1-4</sub> alcohol; an effective physiologically acceptable silicone-based surface active agent, which includes a lipophilic chain containing a silicone backbone, for foaming present in an amount of at least 0.01% by weight of the total composition; water present in an amount to balance the total composition to 100% by weight, where the foamable alcohol compositions optionally include no more than 1% of at least one additional surfactant for adjusting properties of the foam produced from the composition. Claim 1 has also been amended to recite that the composition is foamable when mixed with air at low pressure, which is claim language from claim 2. Claims 52 and 97 have been similarly amended.

Claims 42 to 44 and 77 to 79 (which related to the use of a propellant and/or a pressurized dispenser) have been cancelled without prejudice. Claims 2, 3, 5, 7, 11, 15, 16, 19, 21-26, 31, 32, 34-39, 45-51, 53-54, 58, 66-71, 73 and 82-86 have been also cancelled without prejudice to expedite prosecution of this application.

Claims 1, 4, 6, 8-10, 12-14, 17-18, 20, 27-30, 33, 40, 41, 52, 55-57, 59-65, 72, 74-76, 80-81, 87, 89-98 are pending after entry of this amendment. Claims 9, 55, 56 and 60 have been withdrawn from consideration after the response to the Restriction Requirement.

Claims 1-2, 4-6, 8, 10-18, 20, 27-36, 40-53, 57, 59, 61-68, and 72-98 were rejected under 35 U.S.C. 112, second paragraph on the basis of being indefinite. Those claims have been amended to overcome the indefiniteness rejection and to clarify those claims, or cancelled without prejudice, in order to expedite the present application.

### **Obviousness-Type Double Patenting Rejections**

The Examiner has provisionally rejected claims 1-2, 4-6, 8, 10-18, 27, 29-34, 40-53, 57, 59, 61, 63-66, 72-81, 87-90, 92 and 94-98 on the grounds of nonstatutory obviousness-type double patenting over claims 1-11, 19, 21-26, 32-36, 43-50, 52-57, 59-63 of co-pending U.S. Patent Application No. 11/520,819. Since this is a provisional

rejection, Applicant requests that it be held in abeyance until claims in one or both applications are deemed allowable.

The Examiner has provisionally rejected claims 1-2, 4-6, 8, 10-18, 20, 27-36, 40-53, 57, 59, 61-68, and 72-98 on the grounds of nonstatutory obviousness-type double patenting over claims 1-2, 4-10, 12, 15-25, 29, 31, 33-37, and 39-50 of co-pending U.S. Patent Application No. 11/806,767. Since this is a provisional rejection, Applicant requests that it be held in abeyance until claims in one or both applications are deemed allowable.

The Examiner has rejected claims 1-2, 4-6, 8, 10-18, 20, 27-36, 40-53, 57, 59, 61-68, and 72-98 on the grounds of nonstatutory obviousness-type double patenting over claims 1-107 of Koivisto et al. U.S. Patent No. 7,683,018 and claims 1-132 of Koivisto et al. U.S. Patent No. 7, 199,090 in view of Hoang et al. U.S. Patent No. 5,629,006. Applicant submits that claims 1-2, 4-6, 8, 10-18, 20, 27-36, 40-53, 57, 59, 61-68, and 72-98 in the present application are patentably distinct from the claims of the '018 and '090 patents, even in view of Hoang '006. Applicant submits that it would not have been obvious to a person of ordinary skill in the art to modify the claimed subject matter of Koivisto '018 or Koivisto '090 to include a silicone-based surfactant in the alcohol foam composition or mixture used in the presently claimed methods. Applicant also submits that Hoang '006 teaches away from adding a silicone-based surfactant to the compositions used in the methods claimed by Koivisto '018 and Koivisto '090, and a skilled person would not have had a reasonable expectation of success in making the combination relied upon for this rejection.

The Office Action asserts that it would have been obvious to substitute the fluorosurfactant of the Koivisto patents with another surfactant, i.e., a silicone-based surfactant. The Office Action notes that Hoang et al. teaches that the silicone type of copolymers, i.e., polydimethyl siloxane-polyethylene oxide composed of a siloxane backbone with organic polyalkylene oxide pendants, can provide desired properties, such as low surface tension, high wetting, good dispersing, emulsifying, lubricity, sheen, gloss enhancing; static suppressing, good thermal stability; compatible with organic surfactants and system components, and low toxicity profile. (Office Action, page 13.) The Office Action states:

The instant and conflicting claims differ in that the instant composition claims a silicone-based surfactant, where the conflicting compositions claim an anionic phosphate fluoro-surfactant. However, this deficiency is cured by Hoang et al.

(Office Action, page 11). Applicant submits that this rejection is erroneous.

Claim 1 of Koivisto '018 is drawn to a method of forming or dispensing a skin disinfecting foam containing alcohol, which combines an alcohol-fluorosurfactant mixture with air to form and dispense a skin disinfecting foam containing alcohol. The mixture comprises a physiologically acceptable effective anionic phosphate fluorosurfactant. Likewise, the other independent claims (claims 9, 10, 55 and 99) also recite an anionic phosphate fluorosurfactant. The claims teach that the anionic phosphate fluorosurfactant is sufficient to provide a foam from a mixture having a high concentration of alcohol (greater than or equal to 60% by weight of the total composition). One of ordinary skill in the art would recognize that the anionic phosphate fluorosurfactant (as opposed to another type of surfactant) is important to providing an alcohol foam according to the claimed methods of the Koivisto '018 patent, and it would not have been obvious to substitute a silicone-based surfactant to the composition comprising the anionic phosphate fluorosurfactant.

A person skilled in the art would not find it obvious to substitute a silicone-based surfactant to the composition containing an anionic phosphate fluorosurfactant, nor would she have had a reasonable expectation of success. She would not believe that any and every other surfactant ever made was suitable for substitution in the Koivisto methods.

Hoang '006 shows why a person of ordinary skill would not assume that every surfactant was suitable for addition to the alcohol-fluorosurfactant mixture recited in claim 1 of Koivisto '018; in fact, Hoang '006 specifically teaches away from adding a silicone surfactant to that mixture. Hoang discloses silicone based compounds, but not as "foaming surfactants"; instead, Hoang incorporates them as "block copolymers". Hoang discloses SILWET silicone-based copolymer compounds in column 3, lines 6 to 19. Hoang further discloses various properties of these silicone-based copolymers (some, but not all, of which are cited in the Office Action):

**SILWET surfactants** are nonionic, concentrated, and function in aqueous and non-aqueous systems. SILWET surfactants comprise the following features: low surface tension; high wetting; good dispersing, emulsifying, lubricity; sheen, gloss enhancing; static suppressing; **contribute to antifoaming; moderate profoaming**; broad range of solubility and aqueous cloud points; low volatility, good thermal stability; compatible with organic surfactants and system components, and low toxicity.

(column 3, line 19-27, emphasis added). The Office Action overlooked that Hoang et al. teaches that these silicone-based copolymers are **contributing to antifoaming and moderating profoaming** in the compositions disclosed in Hoang et al. According to Hoang et al., the silicone-based materials in the formulations disclosed in Hoang are **not** contemplated as being foaming agents; to the contrary, Hoang states they are “antifoaming”. This teaches away from the use of a “foaming agent comprising a physiologically acceptable silicone-based surfactant ...” as recited in claim 1 of the present application. Accordingly, a person of ordinary skill in the art would not make the substitution relied upon by the Office Action for this double-patenting rejection. Moreover, the skilled person would not have had a reasonable expectation that adding a silicone-based surfactant would result in a successful method of producing and dispensing a foam using a foamable alcohol composition or mixture, as recited in the claims. Accordingly, Applicant submits that the double-patenting rejection should be withdrawn.

Applicant notes that the Koivisto '090 claims are not limited to “anionic phosphate fluoro-surfactants” as suggested by the Office Action, but rather require specific fluorosurfactants, namely

- $(RfCH_2CH_2O)_x P(O_2)^- (ONH_4)^+_y$  where  $Rf = F(CF_2 CF_2)_z$ ,  $x = 1$  or  $2$ ,  $y = 2$  or  $1$ ,  $x=y=3$ , and  $z = 1$  to about  $7$ ;
- $(CF_3CF_2(CF_2CF_2)_nCH_2CH(OAc)CH_2N^+(CH_3)_2CH_2COO^-)$  where  $n = 2$  to  $4$ ; and
- $RfCH_2CH_2O(CH_2CH_2O)_xH$  where  $Rf = F(CF_2 CF_2)_y$ ,  $x = 0$  to about  $15$ , and  $y = 1$  to about  $7$

The Examiner has provisionally rejected claims 1-2, 4-6, 8, 10-18, 20, 27-36, 40-53, 57, 59, 61-68, and 72-98 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-119 of U.S. Patent Application Serial No. 12/659,063 in view of Hoang et al. US. Patent No. 5,629,006. The Koivisto '063

application is a continuation of the Koivisto '018 and '090 patent discussed above. Its claims are more broadly directed to methods that employ compositions comprising a physiologically acceptable effective fluorosurfactant (contrary to the statement in the Office Action that its claims are limited to anionic phosphate fluoro-surfactants). Some of the dependent claims recite that the effective physiologically acceptable fluorinated surface active agent is selected from the group consisting of fluorinated ethoxylates, glycerol esters, amine oxides, acetylenic alcohol derivatives, carboxylates, phosphates, carbohydrate derivatives, sulfonates, betaines, esters, polyamides, silicones, hydrocarbon surfactants, and combinations thereof. See claims 81, 85, and 93. However, other claims recite an "additional surfactant for adjusting properties of the foam" (see claims 87 and 104), and they are followed by dependent claims reciting particular "additional surfactants" (see claims 88 and 105), none of which are silicone-based surfactants. For many of the reasons set forth above, Applicant submits that a person of ordinary skill in the art would not make the substitution relied upon by the Office Action for this double-patenting rejection. Moreover, the skilled person would not have a reasonable expectation of success. Accordingly, Applicant submits that the rejection should be withdrawn. Alternatively, since this is a provisional rejection, Applicant requests that the rejection be held in abeyance until the allowance of claims in the present application or in the '063 application.

### **Additional Remarks Regarding Hoang '006**

Hoang '006 is directed to a skin disinfecting formulation for use as a skin washing agent, comprising an alcohol, a block copolymer, a foaming surfactant, an emulsifier, a cleaning agent, a polyalkylene glycol, an emollient and water. (Abstract.) Hoang '006 never states that its formulation is mixed with air and dispensed as a foam from a dispenser. As a skin wash, the foam produced from Hoang's formulation would be from rubbing one's hands together, like when a soap is used.

Moreover, Hoang discloses that its formulations contain a relatively high concentration of a foaming surfactant (which is distinct from the polydimethyl siloxane-polyethylene oxide used as a "block copolymer"). The foaming agent is present as from about 5% to about 25% by weight of the formulation, most preferably at about 17 weight

percent. (See col. 1, line 59; col. 4, lines 28-31; and col. 13, lines 37-40.) Applicant has amended the pending claims to further distinguish them from Hoang '006 by reciting that any additional surfactant (a surfactant other than the silicone-based surface active agent) is optional, and when an additional surfactant is present, it is no more than 1% by weight of Applicant's foamable alcohol composition. This amendment is supported throughout Applicant's specification, for example, at page 23, line 18; page 24, lines 20-21; page 26, lines 6-7; and in various examples.

### **Rejection Under 35 U.S.C. 112, second paragraph**

Claims 1-2, 4-6, 8, 10-18, 20, 27-36, 40-53, 57, 59, 61-68, and 72-98 have been rejected under 35 U.S.C. 112, second paragraph on the basis of being indefinite. These claims have been amended and therefore Applicant respectfully requests reconsideration and withdrawal of these rejections.

(1) Claim 1 was said to be indefinite due to the phrase "greater than about". Applicant has amended the claim to remove the word "about".

(2) The Office Action stated that the term "derivative" in claim 18 was indefinite. In response, Applicant has deleted that term from claim 18.

(3) Claims 18, 36, 45, 48, 52, 64-65, 68 and 80 were said to be indefinite because it was unclear if the percentages were relative to the total composition. Applicant has amended the pending claims to make it clear that the recited percentages are indeed relative to the total composition.

(4) Claims 27, 30, 33-34, 42, 66, 72 and 73 were said to be indefinite because they recited ingredients that are not recited in their precedent claims, so the Office Action suggested that the phrase "further" be adopted. Applicant has amended the pending claims as suggested by the Office Action.

(5) Claims 30, 48, 65, 80 and 95 were rejected because the Examiner thought "PEG-200 hydrogenated glyceryl palmate" should be "palmitate". Applicant respectfully submits that the compound was correct as written. PEG-200 hydrogenated glyceryl palmate is one of the chemical components of the commercial product REWODERM LIS 80, which is used in many skin care products. (See enclosed brochure.)

There was no paragraph (6) in the rejection under 35 U.S.C. 112, second paragraph.

(7) Claims 48 and 65 were said to be indefinite because they included “or” in the middle of the recitation of components. Applicant has removed the word “or” and believes claim 65 is now clear. Claim 48 has been cancelled.

### **Rejection Under 35 U.S.C. 102(b)**

The Examiner has rejected claims 1, 5, 11-12, 17-18, 33-36, 40, 42-43, 52, 66-68, and 77-78 under 35 U.S.C. 102(b) as being anticipated by Scholz.

Applicant has amended independent claims 1 and 52 to include subject matter from claim 2, namely that the composition is foamable when mixed with air at low pressure. Claim 2 was not found to be anticipated by Scholz, and Applicant submits that it is clear that Scholz does not disclose a composition that is foamable when mixed with air at low pressure. This is discussed in more detail below. The other rejected claims depend directly or indirectly from claims 1 and 52 (or they have been cancelled). Accordingly, the rejection under 35 U.S.C. 102(b) based on Scholz should be withdrawn.

### **Rejection Under 35 U.S.C. 103(a)**

The Examiner has rejected claims 2, 4, 6, 8, 10, 13-16, 27-31, 41, 45-47, 49-51, 53, 57, 59, 61-64, 72-74, 76, 80-81, 87-93 and 97-98 under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. (U.S. Patent No. 5,951,993) in view of Dubois et al. (U.S. Patent 5,843,881) and Wivell et al. (U.S. Patent No. 5,439,682). The Examiner is requested to reconsider and withdraw these rejections in view of the following comments regarding the differences between the cited references and the claims as amended herein.

### **Surprising Result**

Applicant's foamable alcohol compositions are now found in many institutions where skin disinfection is important, including hospitals, and those foamable alcohol compositions are contained in unpressurized dispensers. When the unpressurized

dispenser is activated by hand operation or automatically, an alcohol foam is dispensed under low pressure. The present invention is especially surprising since alcohol was recognized as a foam breaker or anti-foaming agent by persons of ordinary skill in the art. In essence, the present invention flies in the face of the art by creating a foam from a composition having a high concentration of a lower alcohol.

Several other sophisticated companies filed patent applications directed to foamable alcohol compositions after Applicant filed its priority application (U.S. Provisional Patent Application No. 60/658,580 filed on March 7, 2005). Those other patents and applications confirm that persons of ordinary skill in the art would not and did not expect that an alcohol foam with a high concentration of alcohol could be dispensed under low pressure. To the contrary, these other patents and applications provide evidence that the present methods are surprising and unexpected.

Kimberly-Clark Worldwide, Inc.'s US 20090098067 (paragraphs 0008 to 0009) states:

One problem that has been experienced in the past in formulating foamable cleansers is the ability to incorporate an alcohol into the compositions. Alcohols, for instance, have very effective sanitizing properties. Alcohols, however, are also known defoaming agents making their incorporation into foamable cleansers somewhat problematic. For example, alcohols reduce the surface tension of water in surfactant/water solutions below that needed to maintain the integrity of the lamellae of the foam bubble. Alcohols also displace surfactant molecules at the air/water interface disrupting the stabilization of any foam being formed and causing collapse.

As a consequence, in the past, foamable hand sanitizers containing alcohols have been placed in aerosol containers that produce a pressure high enough to generate a foam. Alternatively, alcohols have been combined with expensive or complicated ingredients in order to facilitate formation of a foam. For instance, those skilled in the art have proposed in the past adding fluorinated surfactants, such as a perfluoroalkylethyl phosphate, to sanitizing compositions containing alcohol.

Kimberly-Clark's reference to fluorinated surfactants may be a reference to Deb's US patent 7,199,090, which is discussed above in the double patenting section, which was the first to disclose a method of producing a foamable hand sanitizer containing a high concentration of alcohol without an aerosol container.



Gojo Industries, Inc. (a leader in hand cleaning) filed US Publication No. 20070148101, which states at paragraph 0005:

Alcoholic products are popular as sanitizers for the skin. However, foaming products based upon alcoholic compositions are problematic, because alcohol is known to have strong defoaming properties. Although aerosol-based alcoholic foams are available, these aerosol products are generally more expensive to manufacture than non-aerosol foams.

Ecolab USA, Inc.'s US Patent No. 7,842,725 (col. 1, lines 20-27) states:

Alcohol antimicrobial products are available as water thin liquids, gels, emulsions, and aerosol foams. Commercially available aerosol alcohol foams, such as QUIKCARE™, commercially available from Ecolab Inc. (St. Paul, Minn.) rely on propellants to generate the foam. Propellants are needed because the surface tension of alcohol is too low for most surfactants to be able to generate foam and sustain it at atmospheric pressure.

US Patent 7,651,990 was filed by 3M Innovative Properties Company, a well known industrial leader. At column 1, lines 26-41, it states:

In the formulation of non-aerosol soap products having a high alcohol content, surfactants have been included in such compositions to facilitate some level of foaming when the compositions are dispensed through a mechanical pump or the like. Surfactants can facilitate at least some degree of initial foaming, but such non-aerosol foams are often unstable and tend to collapse as soon as they are dispensed. While some fluorochemical surfactants have been known to facilitate more stable foams in non-aerosol compositions, fluorochemical surfactants may raise environmental concerns.

There is a need to provide foamable alcohol-containing compositions that are formulated to be anti-microbial and which can be applied to the skin (e.g., the hands). There is a need for alcohol-containing compositions that will form a stable foam in the absence of an aerosol propellant and which will deliver alcohol to the skin for rapid skin disinfection.

3M's discussion of fluorochemical surfactants also may be a reference to the present disclosure.

The Clorox Company's US Patent 7,723,279 states:

For alcohol based hand sanitizers, the Food and Drug Administration (FDA) recommends a concentration of 60% to 95% ethanol, the concentration range of greatest germicidal efficacy. (Food and Drug Administration. Topical antimicrobial products for over-the-counter use;

tentative final monograph for healthcare antiseptic drug products. Federal Register. 1994; 59:31221-2.)

In the past, lower alcohols (C1-C4), such as ethanol, were considered to be de-foamers rather than foam promoting compounds.

In view of this overwhelming evidence that the possibility of producing an alcohol foam with a high alcohol concentration under low pressure and a silicone-based surfactant was not recognized before Applicant's invention, Applicant submits that the presently claimed methods cannot be considered obvious in view of the prior art.

### **U.S. Patent 5,951,993 (Scholz et al.)**

Scholz et al. (hereinafter Scholz) teaches away from the claimed subject matter in several key aspects. First, Scholz's invention provides a viscous composition made viscous using nonpolymeric thickeners (see column 2, lines 31-35) and the formulations have a viscosity of at least 4000 centipoise at 23°C (see column 2, line 45). Scholz does not teach or suggest a composition that is foamable under low pressure. Scholz is directed to **viscous** compositions for skin disinfection. "The invention overcomes the shortcomings of past compositions by providing a **viscous** composition which includes a high concentration of a lower alcohol but does not require a polymeric thickener to make the composition **viscous**." See col. 2, lines 31-35 (emphasis added).

Compositions of this invention have a viscosity of at least about 4,000 cps at 23°C., preferably at least about 10,000 cps, more preferably at least about 20,000, even more preferably at least about 50,000 cps, even more preferably at least about 100,000 cps, and most preferably about 80,000 to about 500,000 cps measured using a very low shear viscometer such as Brookfield LVDV-I<sup>+</sup> viscometer and T spindles with a heliopath adapter.

See col. 5, lines 26-34. Scholz teaches that emulsifiers are provided in combinations that thicken the composition and increase its viscosity to 4,000 cps or more. See, e.g., col. 4, lines 34-38; col. 5, lines 38-50; col. 7, lines 6-9. Scholz also teaches that emulsifiers other than those required to provide a thickener system may be added as emollients or stabilizers. See col. 16, lines 28-30.

Scholz teaches that surfactants can be included in its formulations as emulsifiers, emollients, or stabilizers. In fact, Scholz defines the term "Emulsifier" as being

synonymous with “surfactant”. See col. 4, lines 11 to 12 and lines 32 to 33. Scholz teaches the surfactants or emulsifiers are used to emulsify emollients in several places. See, for example, col. 18, lines 35-39 and col. 19, lines 42-55. There is no teaching whatever regarding using surfactants, of any kind, for foaming.

The Office Action is correct that polyether polysiloxane copolymers are disclosed in Scholz, but they are disclosed as emollients (see col. 18, line 19 to 20), or emulsifiers that stabilize the formulation (see col. 16, lines 28 to 38). Scholz also discloses that polyether/polysiloxane copolymers can stabilize cyclic silicone emollients (see col. 19, lines 45 to 60). There is no teaching whatsoever in Scholz of the presence of a surfactant, let alone a silicone-based surfactant, for foaming of the formulations. At column 7, lines 20 to 43, Scholz notes that the emulsifiers form part of the thickener system and are integral to achieving the high viscosities (which teaches away from being dispensed as foams) and that if the emulsifier does not increase the viscosity, it is considered an emollient or a stabilizer (see col. 7 lines 40 to 43). This teaches away from the idea of using silicone-based surfactants as foaming agents.

Scholz's only teaching with respect to dispensing its viscous formulations as foams is found in col. 21, lines 46 to 67 where Scholz states that its compositions may be “formulated into an aerosol foam or mousse by addition of an appropriate propellant.” Scholz states, “The propellant must be chosen to ensure proper delivery from the container to prevent clogging of the valve.” Col. 21, lines 49-51. When being dispensed as a foam, Scholz's compositions must be mixed with a propellant (see col. 21, lines 47-49). Scholz explains that its preferred propellants result in “a dramatic loss in viscosity making the formulation easy to dispense.” Col. 21, lines 55-58. Scholz explicitly discloses in col. 21, lines 60 to 62 that to dispense the formulations as a foam, they must be combined with a propellant in a pressurized dispenser. Example 35 is the only example of a foam from among 37 examples, and it requires a propellant in a pressurized vessel, as disclosed in col. 48, lines 38 to 40 which teaches the propellant is added and the formulation is placed in a glass pressure vessel. This teaches directly away from the present claims which recite the composition is foamable when mixed with air at low pressure.

### **U.S. Patent 5,843,881 (Dubois et al.)**

Dubois et al. discloses spray compositions for application to the skin, hair or mucosa. The Office Action has cited Dubois for the proposition that it discloses dispensing the spray compositions from both pressurized aerosol and non-aerosol dispensers, and it discloses alcohol levels of 70-85%. (Office Action, page 18.) Applicant submits that Dubois does not disclose a foam dispenser of any kind or a method of dispensing a foam; instead it relates to a liquid spray. Dubois states, "The compositions of the present invention are in the form of products which are sprayed or atomized." Col. 3, lines 32-33; *see also* col. 2, lines 26-28; col. 35, line 45. This is repeated in many places in Dubois, and Dubois defines this phrase as follows: "The term 'spraying or atomizing', as used herein, means to reduce a composition into minute particles, or into a vapor, or into a finely divided liquefied dispersion." Col. 3, lines 17 to 19. Thus Dubois is teaching dispensing the formulations as a spray comprised of droplets and not a foam.

In fact Dubois teaches away from forming or applying a foam. The only reference to "foam" is made in col. 29, line 46-48, in the Section entitled "Other Optional Components", where Dubois teaches that its compositions can include "antifoaming agents".

There is no teaching whatsoever in Dubois related to foamable alcohol compositions. Nothing in Dubois would lead a person of ordinary skill in the art to reduce the viscosity of Scholz. Nothing in Dubois provides a reason to modify Scholz's formulations so they would be foamable when mixed with air under low pressure; to the contrary, Dubois teaches away from such a modification.

### **U.S. Patent 5,439,682 (Wivel et al.)**

Wivell et al. (hereinafter Wivel) discloses compositions for skin cleansing and moisturizing. The compositions contain an anionic surfactant, a suspending agent, a dispersed insoluble oil phase, an additional surfactant, and water. These are the "essential ingredients" of Wivel's formulations as disclosed in col. 2, lines 64 to col. 5, line 54. There are several key distinctions between the present claims and Wivel.

First, Wivel's compositions do **not** include C<sub>1-4</sub> alcohol and there is no teaching whatsoever in Wivell of a composition containing a high concentration of alcohol. Wivell summarizes its invention as follows:

The present invention relates to a personal cleansing composition comprising:

- (a) from about 1% to about 10% of at least one anionic surfactant,
- (b) from 0.4% to about 15% of a suspending agent,
- (c) from about 0.1% to about 10% of a dispersed, insoluble, oil phase,
- (d) from about 1% to about 10% of at least one additional surfactant selected from the group consisting of nonionic surfactants, zwitterionic surfactants, amphoteric surfactants, and mixtures thereof, and
- (e) **the remainder water.**

col. 2, line 64 to col. 3, line 7 (emphasis added). Wivell's composition is water-based, with the above components adding up to about 45%, indicating the composition is about 55% water. Later, Wivell confirms that its compositions have a high water content: "The moisturizing and cleansing compositions of the present invention comprise water as an essential component. The water is present from about 50% to about 99.7%, preferably from about 60% to about 80%, and most preferably from about 65% to about 75%." col. 5, lines 49-53.

The only "alcohols" mentioned in Wivell are longer-chain alcohols (for example, about 10 to about 20 carbon atoms) which are used to prepare anionic surfactants (col. 3, lines 45-55), or polyhydroxy alcohols used as humectants (col. 6, lines 48-50). These are not C<sub>1-4</sub> alcohols. Therefore, Applicant submits that a person skilled in the art would not think Wivel's teachings applied to an alcohol-based composition.

Secondly, while Wivel's formulations may contain silicones, these are disclosed as being emollients, as taught in col. 4, lines 48 to col. 5, line 15. These are contained in the oil phase and provide a skin moisturizing effect. There is no teaching that these silicones can be used to prepare an alcohol composition that is foamable when mixed with air at low pressure. While Wivell teaches that its formulations may be dispensed from a nonaerosol pump foamer or aerosol container, there is no alcohol present, so there is nothing in Wivell to suggest that, if alcohol were present in those formulations, they would be foamable when mixed with air at low pressure. This is significant because alcohol was generally considered by those in the art as a de-foaming agent, as

discussed in detail above. Nothing in Wivell contradicts or is inconsistent with Applicant's showing that persons skilled in the art did not believe an alcohol foam having a high concentration of a C<sub>1-4</sub> alcohol could be dispensed as a foam from an unpressurized dispenser.

In summary, Scholz's formulations specifically contain non-polymeric thickeners to give high viscosities, so the formulations would not be foamable when mixed with air at low pressure. In Scholz, the only teaching where a formulation is dispensed as a foam requires a glass pressure vessel with propellant. Dubois discloses high alcohol formulations, but they are only dispensed as a spray, and the presence of optional "anti-foaming" agents suggest that a foamable composition is to be avoided. Wivell's formulations do not contain any C<sub>1-4</sub> alcohol and contain silicones that are used as emollients. A person skilled in the art would have no reasonable expectation that the unpressurized dispensers in Dubois or Wivell could be successfully used to dispense Scholz's formulation as a foam. Scholz's viscous composition could not be dispensed as a foam by the unpressurized dispensers disclosed by Dubois and Wivel, so the combination relied upon by the Office Action is not operable. Therefore, neither Dubois nor Wivell correct the deficiencies of Scholz in regards to directing one of ordinary skill in the art to the subject matter of the present claims.

### **Other Rejections**

The Office Action makes several other obviousness rejections of various claims based on combinations of Scholz with several other references. None of the other references cure the deficiencies of Scholz set forth above.

The Examiner has rejected claims 1, 42, 44, 52, 77 and 79 under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. (U.S. Patent No. 5,951,993) in view of Tomlinson, R. (WO 85/01876). Tomlinson is cited for its disclosure of a biocidal composition comprising an alcoholic chlorhexidine solution, a quick breaking foaming agent, and aerosol propellant and a corrosive inhibitor. It does not cure the deficiencies of Scholz; to the contrary, Tomlinson discloses a biocidal composition in the form of an aerosol foam produced with an aerosol propellant, not under low pressure. Applicant

has cancelled claims 42, 44, 77 and 79, which were directed to pressurized dispensers and/or corrosion inhibitors. Claims 1 and 52 have been amended.

The Examiner has rejected claims 1, 31-32, 52 and 74-75 under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. (U.S. Patent No. 5,951,993) in view of Hoang et al. (U.S. Patent No. 5,629,006).

The Examiner has rejected claims 1, 17-18, 20, 45, 48, 52, 65, 90 and 94-96 under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. (U.S. Patent No. 5,951,993) in view of Martens et al. (U.S. Patent Publication No. 2005/0031847) and Muller, R. (U.S. Patent Publication No. 2004/0167195).

The Examiner has rejected claims 1 and 82-86 under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. (U.S. Patent No. 5,951,993) in view of Briscoe et al. (U.S. Patent No. 4,440,653).

The Examiner is requested to reconsider and withdraw these rejections in view of the amendment to claims 1 and 52 and the arguments set forth above.

#### **Petition for a Three Month Extension of Time**

Applicant hereby petitions for a three-month extension of time in which to respond to the Office Action of April 15, 2011. The Commissioner is authorized to charge the requisite extension fee, and any necessary fees for this submission, to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.


#### **Conclusion**

Other than the extension fee, Applicant does not believe any fee is required with this submission, but the Commissioner is authorized to charge any necessary fees to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017. The Examiner is invited to contact Applicant's undersigned attorney if any issues remain.

Respectfully submitted,

Date: October 17, 2011

By:



Michael B. Harlin  
Registration No. 43,658

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## **REWODERM<sup>®</sup> LI S 80**

**Viscosity increasing additive for mild  
shampoos or body washes**

- very mild product
- easy to handle at 25 - 35 °C
- nitrogen-free
- vegetable based
- good mucous membrane and skin compatibility

**Goldschmidt Personal Care**

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*This information and all further technical advice is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used. (Status: May 2003)*

**INCI Name**

PEG-200 Hydrogenated Glyceryl Palmate (and)  
PEG-7 Glyceryl Cocoate

**Chemical and physical properties  
(not part of specifications)**

Appearance (20 °C)	slightly yellowish opaque, liquid
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**Properties**

REWODERM® LI S 80 is a liquid additive used to regulate viscosity. It is skin friendly and nitrogen-free. REWODERM® LI S 80 can be easily processed at room temperature.

An average foam height was determined for REWODERM® LI S 80 using the Ross Miles method. REWODERM® LI S 80 has no influence on the foam height in formulations when its concentration is between 1 and 4 %.

Since it is a non-ionic surfactant, REWODERM® LI S 80 is compatible with anionic and amphoteric surfactants. To ensure the stability of the steps in the final product, we recommend to adjust pH of formulations containing REWODERM® LI S 80 between 5.0 and 8.0.

**Application**

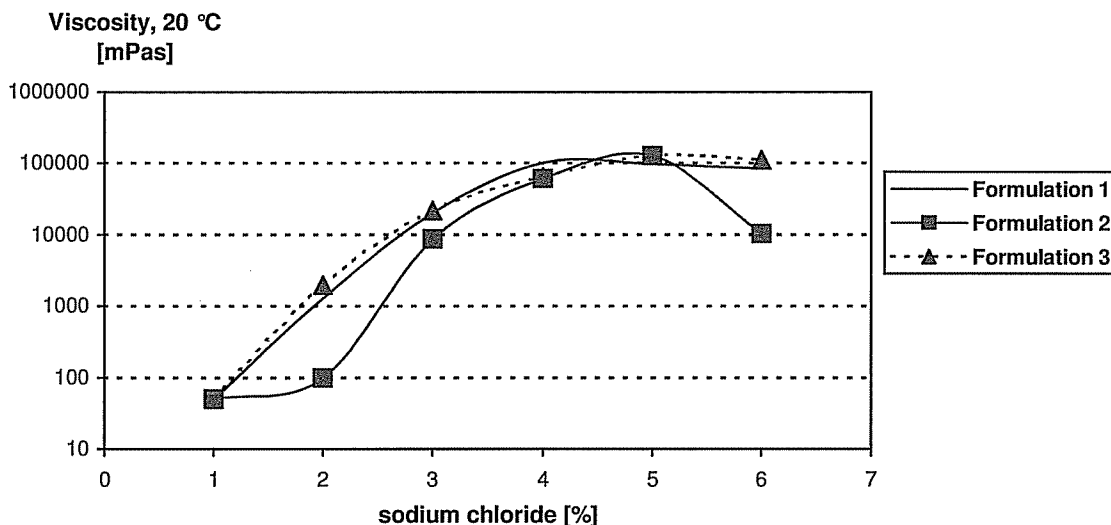
REWODERM® LI S 80 has been developed as liquid thickener, nitrogen-free, that can be processed at room temperature. It is used in:

- Foam baths
- Shower baths
- Hair shampoos
- Liquid soaps
- Baby shampoos
- Cleaning preparations for sensitive skin.

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Examples of the viscosity of formulations with 14 % active matter, based on sodium lauryl ether sulfate, are shown in the following table.



Formulation	I	II	III
Sodium Laureth Sulfate, 28 %	53 %	45 %	45 %
REWOPOL® SB FA 30	-	5 %	-
REWOTERIC® AM 2 C NM	-	-	5 %
REWODERM® LI S 80	2	2 %	2 %
Sodium chloride	1 - 6 %	1 - 6 %	1 - 6 %
Water	to 100 %	to 100 %	to 100 %

#### Suggested usage concentration

When used as a thickening agent, 1 to 4 % REWODERM® LI S 80 are recommended in the final formulation.

#### Packaging

800 kg bulk (4 x 200 kg)

#### Hazardous goods classification

Information concerning

- classification and labelling according to regulations for transport and for dangerous substances
- protective measures for storage and handling
- measures in accidents and fires
- toxicity and ecological effects

is given in our material safety data sheets.

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## Guide Line Formulations

Hair Shampoo, mild	
Sodium Laureth Sulfate, 28 %	25.0 %
TEGO® Betain F (Cocamidopropyl Betaine)	10.0 %
REWOPOL® SB Z (Disodium PEG-4 Cocamido MIPA-Sulfo- succinate)	5.0 %
REWODERM® LI S 80 (PEG-200 Hydrogenated Glyceryl Palmate; PEG-7 Glyceryl Cocoate)	2.0 - 3.0 %
Water, sodium chloride	ad 100.0 %

Preparation: Add all components in the given order with constant agitation. Adjust the pH to approx 6.5 with citric acid and the desired viscosity with sodium chloride.

Shower Gel, mild	
REWOTERIC® AM G 30 (Disodium Lauroamphodiacetate; Sodium Lauryl Sulfate; Hexylene Glycol)	25.0 %
REWOPOL® SB CS 50 K (Disodium PEG-5 Laurylcitrate Sulfo- succinate; Sodium Laureth Sulfate)	7.0 %
REWODERM® LI S 80 (PEG-200 Hydrogenated Glyceryl Palmate; PEG-7 Glyceryl Cocoate)	7.0 %
Water, sodium chloride	ad 100.0 %

Preparation: Add all components in the given order with constant agitation. Adjust the pH to approx 6.5 with citric acid and the desired viscosity with sodium chloride.

Edition: A 05/2000

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